



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-22-22HK; Docket No. CDC-2022-0087]**

**Proposed Data Collection Submitted for Public Comment and  
Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Enhanced Surveillance of Persons with Early and Late HIV Diagnosis. This project collects information from people who were recently diagnosed with HIV at early (stage 0) or late diagnosis (stage 3) to understand barriers to HIV prevention and testing services to contributing to transmission.

**DATES:** CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by Docket No.

CDC-2022-0087 by either of the following methods:

- Federal eRulemaking Portal: [www.regulations.gov](http://www.regulations.gov). Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to [www.regulations.gov](http://www.regulations.gov).

Please note: Submit all comments through the Federal eRulemaking portal ([www.regulations.gov](http://www.regulations.gov)) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7118; E-mail: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each

collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and

## 5. Assess information collection costs.

### Proposed Project

Enhanced Surveillance of Persons with Early and Late HIV Diagnosis  
- New - National Center for HIV, Viral Hepatitis, STD, and TB  
Prevention (NCHHSTP), Centers for Disease Control and Prevention  
(CDC).

### Background and Brief Description

National HIV Surveillance System (NHSS) data indicate that 37,968 adolescents and adults received an HIV diagnosis in the United States and dependent areas in 2018. During 2015-2019, the overall rate of annual diagnoses decreased only slightly, from 12.4 to 11.1 per 100,000. Although not every jurisdiction reports complete laboratory data needed to identify stage of infection, data from most jurisdictions show that many of these cases were classified as Stage 0 (7.9%) or Stage 3 (20.2%) infection (i.e., cases diagnosed in early infection or late infection, respectively). Early and late diagnoses represent recent failures in prevention and testing systems, as well as opportunities to understand needed improvements in these systems.

The NHSS classifies HIV infections as Stage 0 if the first positive HIV test was within six months of a negative HIV test. Persons who received a diagnosis at Stage 0 (i.e., early diagnosis) were able to access HIV testing shortly after

infection yet were unable to benefit from biomedical and behavioral interventions to prevent HIV infection.

The federal initiative "Ending the HIV Epidemic in the U.S." (EHE), prioritizes the provision of HIV preexposure prophylaxis (PrEP), syringe services programs, treatment as prevention efforts, and other proven interventions – as part of the Prevent pillar to prevent new HIV infections of the EHE initiative.

HIV infections are classified as Stage 3 (AIDS) by the presence of an AIDS-defining opportunistic infection or by the lowest CD4 lymphocyte test result. Persons with Stage 3 infection at the time of their initial HIV diagnosis (i.e., late diagnosis) did not benefit from timely receipt of testing or HIV prevention interventions and were likely unaware of their infection for a substantial length of time. Nationally, an estimated 13.3% of persons with HIV are unaware of their infection, contributing to an estimated 40% of all ongoing transmission. Increasing early diagnosis is a key pillar of efforts to end HIV in the United States.

Given the continued occurrence of HIV infections in the United States, the barriers and gaps associated with low uptake of HIV testing and prevention services must be addressed to reduce new infections and facilitate timely diagnosis and treatment. Therefore, CDC is sponsoring this data collection to improve understanding of barriers and gaps associated with new infection and late diagnosis in the era of multiple testing

modalities and prevention options such as PrEP. These enhanced surveillance activities will identify actionable missed opportunities for early diagnosis and prevention, thus informing allocation of resources, development and prioritization of interventions, and evidence-based local and national decisions to improve HIV testing and address prevention gaps.

CDC requests OMB approval for an estimated 3167 annual burden hours. There are no costs to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Burden (in hr)
Persons screened	Recruitment Screener English	2,500	1	5/60	208
Persons screened	Recruitment Screener Spanish	500	1	5/60	42
Enrolled Participant: English Adults	Survey Consent English	2,000	1	15/60	500
Enrolled Participant: Spanish Adults	Survey Consent Spanish	500	1	15/60	125
Enrolled Participant:	English Survey	2,000	1	55/60	1833

English Adults					
Enrolled Participant- Spanish Adults	Spanish Survey	500	1	55/60	458
Total					3167

**Jeffrey M. Zirger,**

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